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BY ECF

Hon. Robert D. DrainU.S. Bankruptcy Court for the Southern District of New York300 Quarropas StreetWhite Plains, New York 10601

Re: In re Purdue Pharma L.P., et al., Case No. 19-23649 (RDD)

Dear Judge Drain:

We represent Dr. Craig Landau, the President and CEO of Debtor Purdue Pharma L.P. ("**Purdue**"). We are compelled to write in response to *The Non-Consenting States' Limited Objection to Motion of Debtors for Entry of an Order Authorizing Implementation of 2022 Key Employee Incentive Plan and 2022 Key Employee Retention Plan (May 11, 2022) [Dkt. No. 4766] (the "Objection").*

The Objection is without factual or legal merit. Although, more than two and a half years since the Petition Date, the "Group of Non-Consenting States" ("NCSG") now contends that Dr. Landau "should not continue as Purdue's CEO," the NCSG and every other stakeholder have benefited in countless ways from Dr. Landau's resolute leadership of Purdue over the course of this bankruptcy. Never before in this proceeding has the NCSG – or anyone else – argued before this Court for Dr. Landau's resignation, and, stripped of its rhetoric, the Objection covers no new ground.

Dr. Landau defers entirely to the Court on the specific question raised by the Debtors' underlying motion [Dkt. No. 4707] (the "Motion"): whether the Debtors' proposed compensation plan for Dr. Landau, which is modeled closely on the compensation plans approved by the Court in 2020 and 2021, is appropriate under the governing law. The NCSG's Objection, however, is riddled with groundless accusations and innuendo that cannot go unaddressed. Dr. Landau is a principled man whose tireless efforts have helped put Purdue in the position to deploy billions of dollars to facilitate abatement of the opioid crisis, and we will not stand idly by as the NCSG makes unfounded smears against him. For the sake of his family,

¹ Objection ¶ 2.

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his colleagues, and his hard-earned reputation for honesty and decency, we must respond on Dr. Landau's behalf.²

I. In His Role as CEO, Dr. Landau Has Made Critical, Value-Maximizing Contributions for the Benefit of All Stakeholders

Dr. Landau is a change agent and a singular leader. Since he assumed the position of CEO of Purdue in June 2017 (after nearly four years as CEO at Purdue Pharma (Canada), a separate, non-debtor entity), Purdue has taken a series of decisive steps, including: ending the company's promotion of opioids by sales representatives to prescribers; eliminating the company's entire opioid sales force; discontinuing the last of the company's opioid-related speakers programs; ceasing the company's sponsorship of all outside pain groups; establishing an internal Office of Corporate Social Responsibility; assembling a new management team; accepting the resignations from the Board of Directors of all remaining members of the Sackler families then holding such positions; renewing the company's focus on R&D; helping develop a plan for diversifying the company's future product portfolio to include therapeutics for certain cancers and disorders of the central nervous system; and prioritizing the advancement of programs intended to address specific elements of the opioid crisis.³

Furthermore, since the Debtors filed for bankruptcy in September 2019, Dr. Landau has helped steer the company towards the goal of maximizing the value of the estates for the benefit of all stakeholders. At the first compensation hearing in this matter, in December 2019, the Court acknowledged the formidable challenges that lay ahead for Dr. Landau and noted the possibility that he might depart the company to pursue more attractive opportunities:

I appreciate that Dr. Landau may be a highly talented CEO who could leave tomorrow, that may be the case. I would hope he wouldn't do that, that he took on the task knowing that it's a monumental task and that he could take some real pride in shepherding this company through a bankruptcy case that sends its value out to the claimants.⁴

True to form, Dr. Landau – who served as a physician in the U.S. Army Reserve Medical Corps for more than 14 years – has not abandoned his post. For more than two and a half years, under circumstances without precedent (including a global pandemic), he has played a crucial role in driving performance and productivity, maintaining employee engagement and morale, limiting attrition as much as possible, and even recruiting new talent. He has made a series of difficult but essential decisions to right-size the company, significantly reducing operating expenses, maintaining the financial viability of the company's various business lines, and delivering financial performance that has exceeded all reasonable expectations, even as the

² The numbered exhibits attached to this submission are cited herein as "Ex. __." Any confidentiality designations that previously applied to these exhibits have been removed by the designating party or parties.

³ See Written Testimony of Dr. Craig Landau Before the U.S. House of Representatives Committee on Oversight and Reform, at 2-3, 4-5, Dec. 17, 2020 ("Written Cong. Testimony") (Ex. 1); see also Hr'g Tr., 80:13-81:3, Sept. 13, 2021 (Debtors' counsel lists examples of Dr. Landau's contributions to the company prior to bankruptcy and notes that "[t]hose are the facts in the record, and they have been in the record for over two years").

⁴ Hr'g Tr., 135:12-18, Dec. 4, 2019.

company shifted significant resources to public health initiatives aimed at combatting the opioid crisis. Indeed, despite the extraordinary costs of the bankruptcy, the Debtors maintain more than one billion dollars of cash on their consolidated balance sheet. Although this "monumental task" – as the Court aptly described it – is certainly not complete, Dr. Landau has provided strong, stable leadership, putting Purdue in the position to deliver billions of dollars in value and critical treatments for the benefit of the American public.

As the Debtors have emphasized, Dr. Landau has played a "vital role in maximizing the value of the Debtors' estates for the benefit of their stakeholders through his stewardship of the Debtors during the many challenges presented by these Chapter 11 Cases"; has been "critical to the Debtors' success"; and has "frankly held the company together in impossibly difficult circumstances."

II. No Creditor Group Has Previously Argued to This Court That Dr. Landau Should Resign

This bankruptcy proceeding was commenced more than two and a half years ago. Yet this is the first time a creditor group has argued before this Court that Dr. Landau should step down from his position as CEO.

At the first compensation hearing in this matter, concerning the Debtors' 2019 compensation plan, the NCSG challenged the proposed terms of Dr. Landau's compensation, but it did not call for Dr. Landau's resignation. Nor did anyone else. The Court stressed this fact at the hearing: "[N]o one is saying he's the type of CEO that just has to go. We're not happy with him. I don't hear that." The Court invited anyone with concerns about Dr. Landau's continuing leadership to raise those concerns directly with the Debtors: "[I]f there is some sort of ground swell that Mr. Landau isn't the right person now, today, that should be known to the debtors, not to me. You should discuss it with the debtors first [T]he record before me doesn't show that." The Debtors' counsel echoed that request. At that time, however, no creditor group took the position before this Court that Dr. Landau should step down.

⁵ Motion ¶ 40.

 $^{^6}$ Motion of Debtors for Entry of an Order Authorizing Implementation of a Key Employee Incentive Plan and a Key Employee Retention Plan, ¶ 32 (Sept. 9, 2020) [Dkt. No. 1674].

⁷ Hr'g Tr., 41:17-18, Dec. 4, 2019.

⁸ Hr'g Tr., 126:19-21, Dec. 4, 2019; *see also id.* at 120:13-16 ("I mean there was I think only one thing that people agreed on in GM at the start of the case, which is the guy who was running GM should go, right. I don't get that sense here.").

⁹ Hr'g Tr., 139:10-14, Dec. 4, 2019.

¹⁰ Hr'g Tr., 36:7-18, Dec. 4, 2019 ("I have personally myself asked various lead representatives of the dissenting states on multiple occasions, I would even use the phrase again and again, the following. If there are things about Dr. Landau that you think we need to know, and you think he engaged in wrongdoing, and you have evidence or documents, you need to tell us because we need to know. Because if actually it turns out that Dr. Landau is a wrongdoer and people have proof of that, there are going to be consequences that might flow from that. The response to request after request after request has been nothing.").

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The next year, after the Debtors moved for approval of the 2020 compensation plan, the Debtors provided the NCSG (among other parties) with several extensions of its objection deadline, and, ultimately, the NCSG did not object to the proposed payments for Dr. Landau, as modified after discussions among the parties 12 – a fact the NCSG neglects to mention in its Objection. The lone party to press an objection to the modified 2020 compensation plan for Dr. Landau was the U.S. Trustee, but the Trustee did not take issue with Dr. Landau's performance as CEO or call for his resignation. Notably, the hearing on the Debtors' 2020 motion was held almost a full month *after* the announcement of the Debtors' plea agreement with the U.S. Department of Justice.

Last year, when the Debtors moved for approval of the 2021 compensation plan, the NCSG objected to the proposed terms of Dr. Landau's compensation, but it did not seek his resignation. Neither did the other two objectors, the State of Washington and the Trustee. By the time of the hearing on the Debtors' 2021 motion, Dr. Landau had testified extensively at a Rule 2004 examination in this matter (on November 24, 2020) and before the U.S. House Oversight Committee (on December 17, 2020). The Court overruled all objections to the 2021 compensation plan for Dr. Landau, and since that ruling, Dr. Landau has continued to lead Purdue with dexterity and distinction, for the benefit of all stakeholders.

III. The NCSG's Objection Is Groundless

Rather than pointing to any new evidence or developments, the NCSG merely cites pieces of the record that have long been available – primarily old, untested allegations concerning pre-petition conduct from one state AG's pleading and carefully pruned snippets of Dr. Landau's testimony taken out of context. As this Court has already ruled, unproven allegations do not provide a basis for denying fair compensation to Dr. Landau, and the NCSG's arguments concerning the evidence do not withstand scrutiny.

A. <u>Untested Allegations Are Not Evidence</u>

In arguing that the below-benchmark compensation for Dr. Landau proposed by the Debtors is inappropriate – and contending for the first time that he should step down as CEO – the NCSG repeatedly cites allegations made by the Colorado AG in an amended complaint filed in July 2019 (the "Colorado Complaint"). ¹³

It is black-letter law that "allegations in the complaint . . . are not evidence." *Hernandez Gomez v. 4 Runners, Inc.*, 769 F. App'x 1, 3 (2d Cir. 2019). The allegations in the Colorado Complaint have never been proven – far from it – and Dr. Landau emphatically disputes any

 $^{^{11}}$ See Am. Agenda for Sept. 30, 2020 Hr'g, ¶ 7 [Dkt. No. 1750]; Am. Agenda for Oct. 28, 2020 Hr'g, ¶ 1 [Dkt. No. 1857]; Agenda for Nov. 17, 2020 Hr'g, ¶ 1 [Dkt. No. 1993].

¹² See Debtors' Supplemental Reply in Support of Motion of Debtors for Entry of an Order Authorizing Implementation of a Key Employee Incentive Plan and a Key Employee Retention Plan, ¶ 1 (Nov. 16, 2020) [Dkt. No. 1960] (reporting that "[n]one of the parties with an economic interest in this case have maintained an objection to the Remaining KEIP Participants' proposed compensation").

¹³ E.g., Objection ¶¶ 9, 10, 11, 12, 13, 14, 24, 26.

suggestion that he participated in any wrongdoing at any time. Indeed, his motion to dismiss the Colorado Complaint was pending when this Court entered the preliminary injunction.¹⁴

At the outset of this case, this Court held that the unproven allegations against Dr. Landau have no bearing on the compensation issue. In opposing the Debtors' first compensation motion, in 2019, the NCSG – alone among the numerous creditor groups – argued that certain allegations against Dr. Landau provided a basis for denying him compensation. The Court rejected the NCSG's contention, emphasizing that the discussion of the allegations against Dr. Landau "isn't affecting my ruling one way or the other." As discussed above, when the Debtors moved for approval of the 2020 compensation plan, the NCSG did not object to the Debtors' modified proposal. Last year, although the NCSG (unsuccessfully) opposed the KEIP payment to Dr. Landau, it avoided dredging up untested allegations.

Now, however, the NCSG seeks to relitigate the issue, even recycling rejected arguments from its 2019 filing.¹⁷ This is improper, as the Court's prior ruling is law of the case. *See Arizona v. California*, 460 U.S. 605, 618 (1983) (pursuant to law of the case doctrine, "[w]hen a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case"); *Aramony v. United Way of Am.*, 254 F.3d 403, 410 (2d Cir. 2001) ("Courts apply the law of the case doctrine when their prior decisions in an ongoing case either expressly resolved an issue or necessarily resolved it by implication."). If anything, the case for disregarding the unlitigated allegations against Dr. Landau is even stronger now, given his extraordinary leadership in the intervening period.

The Court's prior ruling is determinative. Nevertheless, simple fairness compels us to make an additional point: the allegations in the two state-AG complaints against Dr. Landau are highly suspect. (No other state AG named him as a defendant prior to the issuance of the preliminary injunction. Those complaints routinely resort to "group pleading," impermissibly lumping Dr. Landau together with other defendants. They also repeatedly make conclusory allegations that Dr. Landau "directed" or "controlled" others' supposed wrongdoing, without identifying any specific conduct by him. Further, the two AGs' complaints take substantial liberties with the facts; indeed, many of the allegations are contradicted by the very documents upon which they explicitly purport to rely. *See Griffin v. Facebook*, 2020 WL 5645986, at *2 n.4 (S.D.N.Y. Sept. 21, 2020) ("Where the allegations of a complaint are contradicted by documents

¹⁴ Defendant Craig Landau's Motion to Dismiss, *Colorado v. Purdue Pharma, L.P., et al.*, Case No. 18CV33300 (Colo. Dist. Ct. Sept. 16, 2019) ("**Colo. MTD**") (**Ex. 2**).

¹⁵ Statement of the Ad Hoc Group of Non-Consenting States Maintaining Its Objection to Purdue's Wage Motion Insofar As It Relates to Purdue CEO Craig Landau, ¶¶ 5-14 (Dec. 2, 2019) [Dkt. No. 557].

¹⁶ Hr'g Tr., 141:17, Dec. 4, 2019; *see also id.* at 134:15-18 ("It seems to me, first[,] that I don't have the record before me that would come close to suggesting that there should be some thumb on the scales for Dr. Landau because of past events.").

¹⁷ Objection ¶ 25 & n.58.

¹⁸ In its Objection, the NCSG repeats the assertion from its 2019 filing that "multiple" AGs brought suit against Dr. Landau. (Objection ¶ 25 & n.58.) That characterization is highly misleading at best, as the AGs of just two states (Massachusetts and Colorado) − out of the 48 states that brought Purdue-related actions − included Dr. Landau as a defendant prior to the issuance of the preliminary injunction.

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upon which the pleadings rely, the document controls[.]") (internal quotation marks, citation, and ellipses omitted); *accord Peña v. Am. Family Mut. Ins. Co.*, 463 P.3d 879, 882 (Colo. App. 2018); *Galiastro v. Mortg. Elec. Registration Sys., Inc.*, 4 N.E.3d 270, 280-81 (Mass. 2014).

Tellingly, when given the opportunity to explore these allegations with Dr. Landau, who was testifying under oath, the states in the main chose not to do so. On November 24, 2020, Dr. Landau sat for a deposition in this matter conducted by the Massachusetts AG's Office and counsel for the UCC. There were no substantive limitations; all questioners were free to ask Dr. Landau about any and all theories of personal liability and documents of interest. Yet, by and large, they avoided examining Dr. Landau on the allegations against him, presumably because they understood that his testimony would lay bare the serious flaws in those allegations. Dr. Landau's testimony displayed his strong moral character and his unwavering commitment to delivering billions of dollars in value to claimants and communities to help abate the opioid crisis, and it forcefully contradicted any suggestion that he is a wrongdoer.

In sum, as the Court long ago ruled, unlitigated allegations – such as the Colorado allegations that the NCSG rehashes here – have no bearing on the question of whether the proposed compensation to Dr. Landau is reasonable.

B. <u>Several Examples Highlight the Severe Flaws of the NCSG's Objection</u>

We will not address here every instance in the NCSG's Objection of factual errors, mischaracterized evidence, and flawed reasoning. Instead, we highlight several troubling examples.¹⁹

<u>Paragraph 5</u>. The NCSG purports to summarize Dr. Landau's deposition testimony about his reaction to Purdue's conviction in 2007, evidently in an effort to suggest that he did not take that conviction seriously. But his actual testimony on this point – the latter portion of which the NCSG chose not to include in its filing – puts the lie to this criticism:

Q: When Purdue's first criminal conviction happened in 2007, you had been working at Purdue for approximately eight years; is that correct?

did not, as the NCSG asserts, join Purdue as "Executive Medical Director," and his position at that time was not a "leadership role[]." Rather, he joined Purdue as an *Associate* Medical Director, a junior role within the R&D group. *See* Disclosure Statement for Fifth Amended Joint Ch. 11 Plan of Reorganization of Purdue Pharma L.P. and Its Affiliated Debtors, at 55 (June 3, 2021) [Dkt. No. 2983] ("Disclosure Statement"); Written Cong. Testimony at 2 (Ex. 1); Transcript of Rule 2004 Examination of Dr. Craig Landau, at 30:5-6 (Nov. 24, 2020) ("Dep. Tr.") (Ex. 3). The NCSG has blindly repeated a factual error made in the Colorado Complaint – an error that Dr. Landau pointed out two and a half years ago in his motion to dismiss that complaint. *See* Colo. MTD at 3 n.1 (Ex. 2). It also bears emphasis that, as Dr. Landau testified, before he departed for Canada in July 2013, his "main responsibilities . . . were overseeing and advancing the R&D pipeline." Dep. Tr. at 59:10-13 (Ex. 3); *see also The Role of Purdue Pharma and the Sackler Family in the Opioid Epidemic: Hearing Before the H. Oversight & Reform Comm.*, 116th Cong. (Dec. 17, 2020) (oral testimony of Dr. Craig Landau), *available at* https://oversight.house.gov/legislation/hearings/the-role-of-purdue-pharma-and-the-sackler-family-in-the-opioid-epidemic ("Oral Cong. Testimony"), at 2:23:08-13 (Dr. Landau explains that "before becoming CEO [in Canada] I was entrenched in research and development").

- A: Yes.
- Q: You were aware of the criminal conviction about the time it happened in 2007, correct?
- A: Yes.
- Q: How did you feel about the criminal conviction at the time?
- A: Regret. Surprise, since in my understanding, the basis for the conviction was from matters that I wasn't involved in obviously. And a bit of embarrassment.
- Q: You say you felt regret. Why did you feel regret?
- A: On behalf of the company who, you know, admitted to a set of wrongdoing. And as part of the company, I felt regret.
- Q: Did you feel that it was a serious matter at the time?
- A: Of course.²⁰

<u>Paragraphs 6-8</u>. The NCSG contends that Dr. Landau "worked to block" the FDA from requiring mandatory training of physicians as part of the Risk Evaluation and Mitigation Strategies ("**REMS**") program for opioids.²¹ This is demonstrably false.

In its initial notice to Purdue requiring the company to submit a proposed REMS for OxyContin, on October 3, 2008, the FDA did indeed state that the company's proposal should include "[a] plan to ensure that OxyContin will only be prescribed by prescribers who are specially certified[.]"²² Purdue set about to develop a REMS proposal that included such a training requirement, but just two months later, the FDA instructed Purdue to stand down as it considered implementing a REMS not just for individual extended-release opioids, but on a classwide basis.²³

Nevertheless, even after that date, Dr. Landau continued to support a training requirement for physicians. For example, in April 2009, Dr. Landau reported internally that: "Purdue continues its involvement and maintains a lead role in the Industry Working Group (IWG) and Pain Care Forum - REMS Task Force. The recommendations supported by Purdue and introduced into the IWG and PCF discussions include: . . . 2) utilize the DEA as a certification

²⁰ Dep. Tr. at 62:9-63:10 (**Ex. 3**).

²¹ Objection ¶ 8.

²² Letter from Bob Rappaport to Purdue Pharma L.P., at 2 (Oct. 3, 2008) (Ex. 4).

²³ See Center for Drug Evaluation and Research, Summary Review for Application No. 22-272 [OxyContin], at 3, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000SumR.pdf ("On December 4, 2008, the Agency [FDA] issued a letter to the sponsor [Purdue] informing them of our current efforts to develop an opioid REMS for the entire class of long-acting and extended-release opioid products and instructing them not to submit a REMS proposal until they received further guidance from the Agency.").

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body to ensure that all providers and dispensers have had the appropriate education and training related to prescribing and dispensing of controlled substances[.]"²⁴ Likewise, in October 2010, in a formal submission to the FDA's REMS docket, Purdue stated: "FDA should immediately implement the voluntary training as proposed, with a transition to a mandatory training or special certification requirement tied to DEA registration, once the DEA obtains authorization to utilize its registration process to require attestation of qualification by virtue of completion of such FDA-approved training or certification."²⁵

Ultimately, the FDA did not adopt such a training requirement.²⁶ Later, in July 2017, when it was reported that the then-Commissioner of the FDA was once again considering requiring manufacturers to implement doctor-education programs on immediate-release opioids, Dr. Landau reported to Purdue's Board: "Mandatory prescriber education is exactly what we and the twenty-some-odd branded and generic companies proposed to the Agency and its combined Advisory Committees back in 2010 in the context of the soon to be requested Extended-Release/Long-Acting opioid REMS."²⁷

The NCSG's refusal to reckon with this clear documentary record in its Objection is all the more baffling given Dr. Landau's testimony about this topic. At his deposition, when asked whether the authority to prescribe OxyContin is limited to prescribers who are specially certified, Dr. Landau responded:

[I]t's sadly not, despite the fact that Purdue, as a company, along with a variety of other companies both branded and generic, in the context of what we call the industry working group . . . formed at the request of FDA, recommended strongly

 $^{^{24}}$ Email from Dr. Landau to William Mallin (Apr. 28, 2009) (included in PPLPC020000241209-10) (**Ex. 5**).

²⁵ Submission to FDA Docket Number FDA-2009-N-0143 (Oct. 19, 2010) (included in PPLPC001000072550-55) (**Ex. 6**).

²⁶ To date, the FDA has not implemented a mandatory training requirement, although it continues to examine the issue closely. Most recently, in October 2021, the FDA held a two-day public workshop, "Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis." See https://healthpolicy.duke.edu/events/fda-public-workshop-opioid-prescribereducation. Notably, even today, support for a mandatory training requirement is not unanimous. See, e.g., Letter from American Academy of Family Physicians to Acting FDA Commissioner Janet Woodcock (Dec. 2, 2021), No. FDA-2021-N-0951-0040 ("Adding mandatory requirements for training would be burdensome to physicians, many of whom have already sought additional training on pain management practices."); Letter from American Society of Anesthesiologists to Acting FDA Commissioner Janet Woodcock (Dec. 1, 2021), No. FDA-2021-N-0951-0034 ("While ASA has long recognized the magnitude of the opioid epidemic gripping the United States, mandatory prescriber education could result in unforeseen consequences, negatively impacting health care systems and inadvertently affecting the quality and safety of care for patients."); Letter from Boston University School of Medicine (Dec. 3, 2021), No. FDA-2021-N-0951-0054 ("While trying to put our findings into perspective we found a lack of peer-reviewed published evidence supporting the efficacy of mandated continuing education on any topic. We are also concerned that mandated training could decrease access to appropriate opioid therapy for patients with severe pain."); Comments by American Medical Association (Oct. 14, 2021), No. FDA-2021-N-0951-0032 ("The AMA does not believe that a mandatory opioid prescribing REMS will reduce mortality, diversion or improve patient care.") (cited correspondence available at https://www.regulations.gov/docket/FDA-2021-N-0951/comments).

²⁷ Email from Dr. Landau to Mortimer Sackler, et al. (July 10, 2017) (PPLPD008346526-28) (Ex. 7).

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... that REMS training for prescribers be mandatory, and that mandatory training be linked to the DEA registration and/or recertification process. That was a recommendation made I believe in a public meeting to the combined advisory committees and FDA in 2010, and that recommendation was not adopted by FDA. So the REMS that you see today is a product of what the agency requested of the industry.²⁸

Similarly, when asked whether, after emergence from bankruptcy, Purdue should do anything to promote a requirement that OxyContin be prescribed only by prescribers who are specially certified, Dr. Landau testified:

If I were running the business post-emergence, I would work with other sponsors and FDA to implement such a mandatory training system. Not for a single product, but inclusive of one. But for all products. I feel the same way today as I felt in 2010 and the intervening time, that the . . . oftentimes bad outcomes start with the stroke of a pen of a prescriber. Precisely the reason the industry working group, again, branded businesses and generic businesses, often at odds over many things, recommended strongly that training be mandatory. So I think it would be a smart thing to do.²⁹

In its Objection, the NCSG quotes only the first sentence of this second excerpt, misleadingly recasting it as a belated, self-serving reversal in thinking.³⁰ Of course, this requires the NCSG to ignore the rest of Dr. Landau's deposition testimony, as well as the documentary record.

In his testimony before Congress, Dr. Landau made the same points about an education requirement. In his written testimony, he explained:

I also played a leadership role in an industry working group that interfaced with the FDA, resulting in the creation and implementation of a drug safety program – called a Risk Evaluation and Mitigation Strategy ("REMS") – for the class of extended-release and long-acting opioid medications. In that role, dating back to 2010, I supported mandatory training for all opioid prescribers, linked to Drug Enforcement Administration ("DEA") registration.³¹

Similarly, in his oral testimony, Dr. Landau stated:

[T]he company's been very active over the years in risk mitigation and actually played a lead role in the development of what's called the Risk Evaluation and Mitigation Strategy. It was developed, I believe, and finalized at or around 2010. And, in that process, Purdue, along with a number of other companies, proposed

²⁸ Dep. Tr. at 159:23-160:21 (**Ex. 3**).

²⁹ Dep. Tr. at 161:6-24 (**Ex. 3**).

 $^{^{30}}$ Objection ¶ 8.

³¹ Written Cong. Testimony at 2 (**Ex. 1**); *see also id.* at 4 ("[A]s noted above, the company and I have long supported mandatory education for all prescribers of opioids.").

that prescriber education be mandatory in order to prescribe controlled substances and that doing so be linked to the registration process for DEA certification. So... the company, then and now, feels strongly that mandatory education – because, as Representative Connolly talked about in the example of a friend whose son died after being prescribed OxyContin for a sports injury, that prescription may not have been appropriate in the first place. And prescriptions start with the pen of a physician, and physicians need to demonstrate a level of competence before they issue a prescription and before medicines get into the hands of legitimate patients who might not otherwise require or benefit from these medicines.³²

In sum, the record demonstrates Dr. Landau's consistent support for an education requirement for physicians extending back more than a decade, thoroughly debunking NCSG's libelous accusation that he "worked to block it." ³³

<u>Paragraphs 9-14</u>. In these paragraphs, the NCSG simply cuts-and-pastes a series of allegations from the Colorado Complaint, without any independent analysis of the actual underlying evidence. As discussed above, such untested – and deeply flawed – allegations have no bearing on the question before the Court.

Paragraph 15 (and Paragraph 3). The NCSG asserts that "[t]he Sacklers picked Landau to be Purdue's CEO to advance their interests." This contention is evidently tied to the NCSG's later observation that "Landau got his current job, as CEO of Purdue, without having to interview, in 2017." It is hardly remarkable that Dr. Landau – who began working at Purdue in 1999 and who, beginning in July 2013, served as the CEO of Purdue Canada for almost four years – was known to the company's owners by 2017. In any event, the fact that a Board of Directors that included certain Sacklers initially named Dr. Landau as CEO is entirely irrelevant now. The last Sackler left Purdue's Board more than three years ago, in January 2019. The reason Dr. Landau is CEO today is that the company's *current* Board recognizes that he is the right person for the job. And before now, no creditor or other stakeholder had argued otherwise before this Court.

<u>Paragraphs 16-19</u>. Cherry-picking excerpts of Dr. Landau's deposition testimony, the NCSG charges that Dr. Landau is "in denial," or did not care, about certain supposed facts. The full record demonstrates otherwise.

For instance, the NCSG criticizes Dr. Landau's response to a question concerning whether he has "ever tried to figure out whether Purdue caused the opioid crisis," but the NCSG

³² Oral Cong. Testimony at 1:42:26-1:43:34.

³³ Objection ¶ 8.

³⁴ Objection ¶ 3.

³⁵ Objection ¶ 15.

³⁶ See Disclosure Statement at 60.

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highlights only the first sentence of his answer,³⁷ omitting the substance of his detailed discussion of this topic:

[C] ausation, from a legal perspective, is - is something best left to those with the experience or expertise to consider.

My view is that the answer is while our products, one or another product has been the subject of a significant abuse, misuse, and diversion with consequences, that Purdue did not cause the opioid crisis.

The crisis is complex and multi-factorial. It's acknowledged to have multiple factors needing to be considered, whether they be sociological, financial, or economical behavior, or biologic, access to healthcare, and others. It's a tragedy no matter how you slice it, and we are doing our best to address it.³⁸

As another example, the NCSG evidently takes the view that Dr. Landau's deposition testimony that "I can't recall a time when I thought what I was doing was anything but appropriate and well-intentioned and good" is false.³⁹ But the NCSG does not explain what it believes to be inaccurate about that statement, much less point to any actual evidence supporting its view. Notably, when Dr. Landau gave this testimony, the questioner (from the AG's Office for Massachusetts, a member state of the NCSG) did not confront Dr. Landau with any evidence contradicting it. The truth is, Dr. Landau has had numerous achievements at Purdue that serve the public good – and not just in his recent years as CEO. For example, Dr. Landau played a key role in the years-long process of developing and obtaining approval for reformulated OxyContin, which the FDA, in 2013, recognized to have abuse-deterrent properties.⁴⁰ This breakthrough was widely welcomed as an important advance, including by almost every state that is now a member of the NCSG. In a March 11, 2013 letter to the FDA, forty-eight state and territorial attorneys general recognized that "the development of tamper-resistant drugs provides an opportunity" and that "[a]dding new physical and chemical features to prescription opioids to deter abuse could reduce misuse of these drugs and the sometimes deadly consequences," and the group encouraged the FDA to assure that not only branded opioids but also generics are designed with abuse-deterrent features.⁴¹

Dr. Landau's testimony – not only at his deposition, but also before Congress – reveals that he is a serious-minded, clear-eyed leader who is firmly committed to doing his part to combat the opioid crisis.

<u>Paragraph 20</u>. The NCSG selectively quotes from a preliminary "Diagnostic and Forward Plan" drafted by Dr. Landau in May 2017, before he was named CEO of Purdue in the

³⁷ Objection ¶ 19.

³⁸ Dep. Tr. at 99:7-100:6 (**Ex. 3**).

³⁹ Objection ¶ 18.

⁴⁰ See, e.g., Written Cong. Testimony at 2 (Ex. 1).

⁴¹ Letter from National Ass'n of Attorneys General to FDA Commissioner Dr. Margaret Hamburg (Mar. 11, 2013) (**Ex. 8**).

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U.S. 42 The NCSG highlights Dr. Landau's reference in that document to an "opioid consolidation strategy," but ignores the actual details of Dr. Landau's presentation, which included proposals to: "[r]estore appropriate focus on the patient, patient access and the proper practice of pain management across the global organization"; adopt a "guidelines-based" patient-centric program first used at Purdue Canada under Dr. Landau's leadership; "[c]urtail traditional opioid product detailing by sales representatives"; "revive" the company's initiatives in epidemiology and abuse-deterrent formulations; and "creat[e] a company focused entirely on abuse deterrent opioid and non-opioid analgesic therapeutics."⁴³ A fair reading of this document – to be distinguished from the NCSG's misleading depiction – reveals a set of forward-thinking ideas presented by the future leader of the company.

<u>Paragraph 22</u>. The NCSG faults Dr. Landau for not implementing a "we stand by our patients" program that Jonathan Sackler included in a long "list of ideas" set out in a November 4, 2018 email. However, the NCSG presents only part of the story, omitting critical context.

It is highly ironic that the NCSG now blames Dr. Landau for not implementing an idea put forward by a Sackler. In any event, in fixating on a single idea (among many) floated in a single email, the NCSG misses the larger picture. In testimony that is not included in the NCSG's filing, Dr. Landau testified that although Purdue did not pursue the particular program mentioned in Mr. Sackler's email:

Purdue has, over the last two or more years under our corporate social responsibility umbrella, provided substantial support to third-party organizations where that support is geared to funding, you know, treatment, MAT recovery, back-to-work training, and even care for children in the context of a mother or a parent, you know, who is suffering from OUD.⁴⁴

Furthermore, independent of Mr. Sackler's email, Purdue under Dr. Landau's leadership carefully considered how best to use its resources to help mitigate elements of the opioid crisis and ultimately decided to pursue three important public-health initiatives: (1) developing, manufacturing, and distributing Medication Assisted Treatment in the form of generic suboxone, making millions of doses available; (2) supporting the development and production of intranasal naloxone, to be made available without a prescription; and (3) developing and providing at low or no cost a second-generation version of nalmefene, an opioid overdose reversal medicine. Dr. Landau explained this at his deposition when he was asked about Mr. Sackler's email – highly relevant testimony that the NCSG, once again, has not cited:

What I can say is that we – by November 4th, 2018, we were in the process, and far down the road, of considering how best to put the company's resources and output

⁴² See Official Committee of Unsecured Creditors' Notice of Filing of Sixth Set of Partially Redacted Exhibits to the Declaration of Arik Preis Dated November 18, 2020, Ex. 137 (Feb. 25, 2021) [Dkt. No. 2419-1] (**Ex. 9**).

⁴³ *Id.* at PWG00467087-88.

⁴⁴ Dep. Tr. at 147:5-15 (**Ex. 3**).

to the best possible use to address the, you know, the issues that, you know, rolled up to this public health crisis.

And, you know, some of the examples I am certain you are familiar with, but providing free substantial and free generic Suboxone, helping to develop and bring to bear low-cost over-the-counter intranasal naloxone, so it's much more widely accessible without a prescription.

And developing a next generation opioid antagonist or opioid overdose reversal agent, you know, targeted at the current killer which is, you know, which are often synthetic opioids like fentanyl and carfentanil and its derivatives.

So this was a matter, to me, of how can the company direct its most – the most of its resources and apply most of its focus for the greatest good. 45

<u>Paragraphs 23, 25, 27, and 28</u>. The NCSG criticizes Dr. Landau for not leading an investigation into misconduct at Purdue, but this is by now well-trodden ground.

In its partial objection to the Debtors' KEIP motion last year, the NCSG argued that compensation should be withheld from Dr. Landau because he had not conducted an inquiry into wrongdoing at Purdue. ⁴⁶ The Court was presented with thorough briefing and argument on investigations into possible past misconduct and whether Dr. Landau should be involved in such investigations. This included a detailed discussion about the respective roles of the U.S. Department of Justice, state Attorneys General, creditor groups, the Special Committee of Purdue's Board of Directors, and the company's outside counsel. The Court's 2021 ruling on this point definitively dispensed with the NCSG's arguments:

The Debtors have quite cogently pointed out that because Dr. Landau was himself named as a defendant in some complaints against Purdue and the Sacklers, prepetition, albeit that he strongly denies the claims that were asserted against him in that litigation, it would have been improper for him to inject himself into the process of determining who acted properly or improperly at Purdue, who was still an employee there. I agree with that argument. That role really needs to have been assumed by other parties, whether that would be the Special Committee or outside counsel, as opposed to by Dr. Landau.

There is no evidence before me to show that any current employee does deserve to be fired or any evidence that the Debtors have turned a blind eye to any improper past conduct. Indeed, it appears the Debtors have been very attentive and responsive to allegations of specific – regarding specific current employees' alleged past improper conduct, as well as to any allegations of current improper conduct.

⁴⁵ Dep. Tr. at 148:4-149:12 (Ex. 3); see also Written Cong. Testimony at 3 (Ex. 1).

⁴⁶ The Non-Consenting States' Limited Objection to Motion of Debtors for Entry of an Order Authorizing Implementation of 2021 Key Employee Incentive Plan (Aug. 20, 2021) [Dkt. No. 3625].

Ultimately, o[n] this record, I do not believe that there[] is sufficient evidence to deny the Debtors' motion as to Dr. Landau. On the other hand, I will note that since the first order granting a [KEIP] motion, and this will be the case for this order, I have provided for disgorgement if it turns out later that any recipient of a payment has engaged in misconduct. And the current language was further beefed up in my order approving the KERP motion, and will be in this order as well.

If any party believes that these Debtors are continuing to employ[] people who should not be employed because of their role in prior misconduct, that issue should be addressed with a proper evidentiary record and not by insinuation or innuendo or request to prove a negative.

It's a serious issue and should be addressed with the seriousness that it warrants, i.e., with a proper and full record[.]⁴⁷

As noted by the Court, the KERP and KEIP orders last year were "beefed up" to prohibit payments to any participants believed by Purdue, based on a reasonable inquiry (including inquiry of its attorneys and advisors), to have knowingly participated in any criminal misconduct in connection with his or her employment with the company, or to have been aware of (other than from public sources), and not reported, fraudulent or criminal acts or omissions with respect to the company's commercial practices in connection with the sale of opioids. ⁴⁸ That prohibition is, of course, preserved in this year's entered and proposed orders. ⁴⁹ What's more, the Debtors' counsel has spoken unequivocally about the consequences that would flow from the discovery that a current employee had been involved in wrongdoing: "Let me be very clear. If we believed that a current employee committed a crime or was aware of [a] crime or fraud and did not report it, they would be fired." ⁵⁰

Heedless of the Court's ruling last year, the NCSG now raises the issue again but points to no factual developments that should alter the Court's prior ruling.

<u>Paragraph 24</u>. The NCSG quotes the Court's observation at the September 13, 2021 compensation hearing that, prior to 2017, "the corporate culture of Purdue was sick," ⁵¹ and then asserts that "Landau was an author of that culture." The NCSG, however, has misleadingly

⁴⁷ Hr'g Tr., 139:7-140:17, Sept. 13, 2021.

⁴⁸ Order Authorizing the Debtors to Implement 2021 Key Employee Retention Plan, ¶ 9 (Aug. 16, 2021) [Dkt. No. 3571]; Order Authorizing the Debtors to Implement 2021 Key Employee Incentive Plan, ¶ 8 (Sept. 15, 2021) [Dkt. No. 3770].

⁴⁹ Order Authorizing the Debtors to Implement 2022 Key Employee Retention Plan and 2022 Key Employee Incentive Plan, ¶ 10 (May 20, 2022) [Dkt. No. 4862]; *see also* Proposed Order Authorizing the Debtors to Implement 2022 Key Employee Incentive Plan and 2022 Key Employee Retention Plan, ¶ 12 (Apr. 27, 2022) [Dkt. No. 4707-1].

⁵⁰ Hr'g Tr., 41:12-15, July 29, 2021.

⁵¹ Objection ¶ 24 (quoting Hr'g Tr., 138:5-6, Sept. 13, 2021).

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truncated the Court's remarks. Immediately after the comment quoted by the NCSG, the Court continued:

It is important, obviously, to change that culture, and there is considerable evidence in the record that, in fact, under Dr. Landau's leadership such changes have taken place, including the pre-petition termination of the opioid sales force, the end of detailing, and the like.⁵²

Exactly so.

At the same hearing, one member of the NCSG – the State of Washington – argued that Dr. Landau and Purdue's General Counsel (Marc Kesselman) were responsible "for directing the actions and setting the culture of a company that has caused untold destruction and immiseration." In sharp terms, the Court rebuked Washington for ignoring the facts:

What the state of Washington got wrong and, indeed, its assertion is scurrilous in light of its failure to get it right, is that Mr. Kesselman arrived at Purdue in 2018, well after the conduct that it rightly complains of. Similarly, Dr. Landau became CEO of Purdue in June of 2017, well after the conduct that is the subject or was the subject of a DOJ investigation and the decades of misconduct referred to in the objection. Why would anyone having the role of an attorney general of a state make such allegations is perhaps better left for the voters. ⁵⁴

Disregarding the Court's pointed remarks, the NCSG has now doubled-down on this line of argument. As before, it should be summarily rejected.

<u>Paragraph 29</u>. The NCSG asserts that Dr. Landau has "twenty years of culpability for building the Sackler Pharma Enterprise." It suffices to say that this absurd statement, untethered from any evidence, exceeds all bounds of reasonable advocacy. Dr. Landau certainly did not "build" the Sacklers' businesses, and no one with even a passing familiarity of the record in this case could fairly argue otherwise.

Wildly exaggerating Dr. Landau's role in one breath, the NCSG baselessly diminishes it in the next. The NCSG concedes that during Dr. Landau's tenure as Purdue's CEO, the company ceased promoting opioids and eliminated its opioid sales force, ⁵⁵ but it downplays Dr. Landau's responsibility for implementing these important changes. The NCSG contends that the "real reason" that the sales force was eliminated was a January 30, 2018 presentation to the

⁵² Hr'g Tr., 138:8-12, Sept. 13, 2021; *see also id.* at 113:6-8 (Court notes that "the Debtors have identified many steps that I think were quite far-reaching that Dr. Landau took to change the culture").

⁵³ The State of Washington's Objection to Motion of Debtors for Entry of an Order Authorizing Implementation of 2021 Key Employee Incentive Plan, ¶ 5 [Dkt. No. 3624].

⁵⁴ Hr'g Tr., 134:4-13, Sept. 13, 2021.

⁵⁵ See, e.g., Disclosure Statement at 55 ("Under [Dr. Landau's] leadership, the company voluntarily stopped promoting opioid pain medications to prescribers through sales representatives and via other channels, such as in medical journals [and] eliminated its opioid medication sales force[.]").

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Board, "which has never been made public" ⁵⁶ and about which Ilene Sackler commented: "It seems to me, based on several things presented today, that promoting any opioids, in any way, in any country should be stopped immediately." ⁵⁷ Setting aside the manufactured intrigue – the NCSG has access to every document produced in this matter, regardless of its confidentiality designation – the NCSG ignores documents in the public record that demonstrate Dr. Landau's foresight and leadership on this issue. For example, even before he was appointed CEO, Dr. Landau recommended to Purdue's Board that the company should "[c]urtail traditional opioid product detailing by sales representatives." ⁵⁸

At the first compensation hearing, in December 2019, the Debtors' counsel noted that Dr. Landau "oversaw as the CEO of the company the entire dismantling of the sales force, the firing of the entire sales force, [and] the cessation of promotion." If the NCSG had any doubts about this account, the time to challenge Dr. Landau was at his deposition. Not one question, however, touched on this issue.

<u>Paragraph 30</u>. Finally, the NCSG suggests that Dr. Landau's continued leadership of Purdue is somehow disrespectful to victims of the opioid crisis. In fact, however, Dr. Landau has played an instrumental role in laying the groundwork for the creation of a public benefit company that not only will provide substantial funds to the abatement trusts, but also will develop and provide, at or below cost, life-saving medicines for the treatment of opioid use disorder and for reversing overdoses. Dr. Landau is a physician by training, and, as he has made clear in public statements, the victims are never far from his mind. He has spoken repeatedly, and unflinchingly, about the horrific toll of the opioid crisis. For example, before the U.S. House Committee on Oversight and Reform in December 2020, Dr. Landau testified:

I would like to start by recognizing and thanking the individuals who have shared their stories, their stories of loss, and their stories of addiction. They are heartbreaking, and I have no words. I can't imagine the pain

One very important risk associated with the use of opioids is addiction. I've listened to individuals in recovery describe their struggle with addiction. In meetings both public and private, I've heard heartbreaking stories like we've heard today from grieving parents whose children died from an opioid overdose.

As a father, and as a human being, I can't imagine the despair, the emptiness, and the anger these parents must feel every single day of their lives. Each and every instance of addiction, of overdose and death is a human tragedy, for the individual, for their families, and for all of us as a society. And with this in mind, I'd like to address those who've been directly affected by the opioid crisis. As stated earlier,

⁵⁶ Objection ¶ 29.

⁵⁷ Objection, Ex. 2.

⁵⁸ **Ex. 9** at PWG004670888.

⁵⁹ Hr'g Tr., 41:12-15, Dec. 4, 2019.

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on November 24, Purdue pled guilty to three felonies in federal district court based on certain past practices related to its opioid medicines.

To everyone listening who has been impacted by the opioid crisis, I want to be clear, and I want to speak directly to you. On behalf of Purdue, as its current leader, I am profoundly sorry. In trying to strike a careful balance between supporting physicians who treat patients with pain and mitigating the serious risks associated with the opioid medications, Purdue fell short. The company accepts full responsibility for its wrongdoing, and as Purdue's leader, I'm determined to lead all of our efforts to help address the opioid crisis as quickly and effectively as I can.⁶⁰

And Dr. Landau will continue to follow through on his commitment to victims to the very best of his ability.

* * *

In conclusion, we make this submission to right the record. The NCSG's caricature of Dr. Landau bears no resemblance to the actual person – a strong, principled leader who has helped Purdue chart a new course.

Respectfully submitted,

/s/ Linda Imes

Linda Imes Christopher Dysard Reed Keefe

cc: All Counsel (by ECF)

⁶⁰ See Oral Cong. Testimony at 36:24-36:41, 37:55-39:33.